

REMARKS

Claims 43, 51, 52, and 54-61 are pending in the application. Claim 43 is amended for clarity and to address other issues raised by the Examiner. Basis for the amended claim can be found in the specification and in the original and previously pending claims. No new matter is added.

Rejections under 35 U.S.C. §103(a)

Claims 43, 51, 52, 54-61 are rejected under 35 U.S.C. §103(a) as being unpatentable over Northrup (US Patent 5,593,424) in view of Stevens et al. (US Patent 5,769,812). The disclosure of the Northrup and Stevens singly or in combination fail to teach or suggest all elements as claimed.

Northrup or Stevens, both alone and in combination, fail to disclose or suggest deploying a plurality of anchors from an anchor deployment mechanism onto the annulus such that each of the deployed anchors penetrates a portion of the tissue of the annulus. In Northrup, the anchor (i.e. suture support device) does not penetrate the annulus tissue. Rather, the anchor rests atop the tissue and a filament (i.e. suture) penetrates the annulus tissue. The filament is a suture with a swaged-on needle that affixes the anchor to the underlying heart tissue. The needle with attached suture penetrates through a first hole in the anchor, down through the underlying tissue where it loops back around to insert back up through the second hole in the anchor. Further, Figures 10 and 11 of Northrup show the suture and anchors are positioned on the valve leaflets on either side of the leaflet commissure, not on the annulus. Figures 10 and 11 do not show a plurality of anchors penetrating the annulus tissue.

Northrup and Stevens, both alone and in combination, also fail to disclose or suggest threading a single filament through each of the deployed anchors such that the filament does not penetrate the tissue of the annulus, as recited in claim 1. As discussed in the interview, Northrup discloses in the embodiment of Figures 1-9 that a plurality of filaments rather than a single filament are threaded through the anchors. Moreover, the filaments in Northrup penetrate the annulus tissue in contrast to the claimed method where the filament does not penetrate the tissue of the annulus. The Northrup procedure requires that the filament penetrate the tissue of the annulus in order for the filament to shorten the tissue when tightened. It would not be possible to modify Northrup so that the filament does not

penetrate the tissue of the annulus, as this would make it impossible for the Northrup procedure to accomplish its goal of shortening the annulus.

In addition, Northrup alone or in combination with Stevens does not disclose, teach or suggest advancing a catheter comprising an interventional tool having an anchor deployment mechanism through the patient's vasculature into the heart from a femoral venous location wherein the anchor deployment mechanism carries a plurality of deformable anchors, as recited in claim 1. Northrup relates to a procedure that is performed surgically and has no disclosure whatsoever related to advancing the catheter through the patient's vasculature into the heart from a femoral venous location. The examiner asserted that it would have been obvious to modify Northrup with the percutaneous access method of Stevens. However, neither Stevens nor Northrup has any disclosure related to an interventional tool having an anchor deployment mechanism that carries a plurality of deformable anchors. As discussed, Northrup is a surgical procedure that does not use a catheter. Stevens makes no mention of any type of tool that can be used to deploy an anchor.

It would not be obvious to modify the method of Northrup such that an interventional tool having an anchor deployment mechanism is advanced via a femoral approach. The engineering needed to adapt the suturing device of Stevens (which was only mentioned in passing) to perform the method of Northrup is beyond what would have been obvious to one of ordinary skill in the art. Further, the stapling device shown in Figure 7 of Stevens would not have been capable of performing the running mattress suture method described by Northrup to affix the suture support element to the valve annulus. The apparatus disclosed in Stevens would need to be completely redesigned in order to "adapt" it for use with the Northrup device and method. Such a redesign is beyond the scope of both Northrup and Stevens.

Even if one of ordinary skill in the art were motivated to modify the Northrup apparatus and method to be capable of deployment on the annulus through a femoral venous location, the modifications necessary to adapt the Northrup apparatus for deployment on the annulus through a femoral venous location would not have been obvious to one of ordinary skill in the art at the time of the invention. Both Stevens and Northrup provide insufficient detail to enable or motivate one of ordinary skill in the art to modify the Northrup devices and method or the Stevens devices or method for deployment on the annulus through a femoral venous location.

In addition, neither Northrup nor Stevens disclose or suggest a deformable anchor as in claim 1. The Northrup procedure must be used with anchors that are non-deformable so that the anchors do not buckle when suture is threaded through the two suture holes and tied. [Northrup, col. 4, lines 64-67.] Northrup further states that the suture support segment must be non-deformable without any possibility of additional longitudinal shortening of the tissue annulus due to excessive tension during knot-tying. [Northrup Col. 7, lines 19-26.]

Thus, the combination of teachings of Northrup and Stevens cannot and does not result in any of the instantly claimed methods. Applicant asserts that the rejection of claim 1 should be withdrawn. The Examiner also rejected claims 51, 52, 54-61 over Northrup in view of Stevens. Claims 51, 52, 54-61 are patentable over the cited art based on their dependency on claim 1 as well as on their own merit.

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Response to Office Action

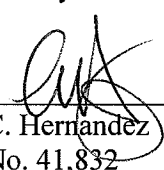
CONCLUSIONS

Entry of this amendment and examination of the application are respectfully requested. The above is believed to be a complete response. In view of the amendments and remarks herein, Applicants believe that all claims are now in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken by the Examiner are not to be construed as acquiescence with outer positions of the Examiner that have not been explicitly contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims. The Examiner is invited to telephone the undersigned to resolve any remaining issues and/or informalities and expedite prosecution of this case.

Please apply any charges or credits to Deposit Account No. 50-0311.

Respectfully submitted,

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